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Application No.	2001/0916
Date of Filing	18 October 2001
Applicant	ATROPOS LIMITED, an Irish Company of Unit 4, Sunnybank Centre, Bray, County Wicklow, Ireland.

Dated this 6 day of February 2002.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

 X the grant of a patent under Part II of the Act

 the grant of a short-term patent under Part III of the Act on the basis of the information furnished hereunder.

1. Applicant(s)

Name ATROPOS LIMITED

Address Unit 4
Sunnybank Centre
Bray
County Wicklow
Ireland

Description/Nationality

An Irish Company

2. Title of Invention

" A Device"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date

Country in or for
which filed

Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed
by Applicants(s) to be the inventor(s)

Name: John Butler, an Irish citizen of

Address: 16 Holly Park, Blackrock, County Dublin, Ireland.

Name: Aoibheann Gill, an Irish citizen of

Address: Rathcline, Lanesboro, County Longford, Ireland

5. Statement of right to be granted a patent (Section 17(2) (b))

The Applicant derives the rights to the Invention by virtue of a Deed of Assignment dated October 17, 2001.

6. Items accompanying this Request – tick as appropriate

- (i) X Prescribed filing fee (£100.00)
- (ii) X Specification containing a description and claims
 Specification containing a description only
 X Drawings referred to in description or claims
- (iii) An abstract
- (iv) Copy of previous application (s) whose priority is claimed
- (v) Translation of previous application whose priority is claimed
- (vi) X Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant (s))

7. Divisional Application (s)

The following information is applicable to the present application which is made under Section 24 –

Earlier Application No:

Filing Date:

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name

John A. O'Brien & Associates

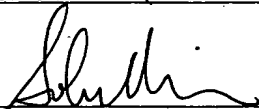
Address

The address recorded for the time being in the Register of Patent Agents, and currently Third Floor, Duncairn House, 14 Carysfort Avenue, Blackrock, Co. Dublin, Ireland.

9. Address for Service (if different from that at 8)

As above

Signed



JOHN A. O'BRIEN & ASSOCIATES

Date October 18, 2001

"A Device"Introduction

5 This invention relates to a colonic overtube for maintaining a sigmoid colon in a straightened configuration.

10 Conventional colonoscopy procedures involve advancing a colonoscope through the floppy sigmoid colon to the proximal end of the descending colon. During advancement of the colonoscope through the sigmoid colon loops often form in the floppy sigmoid colon. It is difficult to then advance the colonoscope further, into the descending colon, due to the looped nature of the sigmoid colon. Further pushing of the colonoscope simply increases the loops in the sigmoid colon without advancing the colonoscope into the descending colon. The sigmoid colon is generally
15 straightened by manipulation of the colonoscope, however advancing the colonoscope further, into the descending colon may cause the loops in the floppy sigmoid colon to reform.

20 It is known to use a stiff overtube to prevent the reformation of loops by splinting the straightened sigmoid colon. The overtube is advanced over the colonoscope until the distal end of the overtube is at the proximal end of the descending colon. The overtube maintains the sigmoid colon in the straightened configuration and prevents loops from reforming in the sigmoid colon during advancement of the colonoscope further, into the descending colon.

25 However, parts of the interior wall of the colon may become trapped between the colonoscope and the overtube during advancement of the overtube over the colonoscope, which may result in shearing off of the trapped part of the colon wall or puncturing of the colon wall.

30

Furthermore, kinking of the stiff overtube often occurs during advancement through the potentially tortuous path through the colon.

5 This invention provides a colonic overtube which is aimed at overcoming at least some of these disadvantages.

Statements of Invention

10 According to the invention, there is provided a colonic overtube, the overtube:-

having a proximal end for location externally of a colon, and a distal end for insertion into a colon; and

15 having a colonoscope lumen extending therethrough for advancing the overtube over a colonoscope;

the overtube being configured to maintain a sigmoid colon in a straightened configuration; and

20 the overtube comprising a seal at the distal end of the overtube for sealing between the overtube and a colonoscope extending through the colonoscope lumen.

25 The colonic overtube of the invention has a seal at the distal end of the overtube. The seal ensures that no parts of the colon wall become trapped between the overtube and the colonoscope during advancement of the overtube over the colonoscope. This arrangement prevents shearing off of the trapped part of the colon wall or puncturing of the colon wall.

30

In one embodiment of the invention the seal is fixed to an exterior surface of the overtube, the seal extending inwardly to effect a seal between the overtube and a colonoscope extending through the colonoscope lumen.

5 The seal may extend distally of the distal end of the overtube.

In a preferred embodiment the seal comprises an inner sealing layer and an outer sealing layer surrounding the inner sealing layer. Ideally the seal comprises a tubular sheath, the sheath being folded over to define the inner sealing layer and the outer sealing layer.

10 The overtube preferably comprises a rounded tip at the distal end of the overtube for atraumatic advancement of the overtube through a colon. Most preferably the tip is fixed to an exterior surface of the overtube, the tip extending around the distal end of the overtube at least partially into the colonoscope lumen.

15 The rounded tip at the distal end of the overtube ensures that the overtube advances atraumatically through the colon. Any inadvertent contact between the distal end of the overtube and the interior wall of the colon will not result in damage or trauma to the colon.

20 In another embodiment of the invention the overtube defines at least one corrugation for kink resistance during advancement of the overtube through a colon. Ideally the corrugation extends along the overtube in a convoluted manner. In another case the corrugation extends around the overtube in a loop. Most preferably the overtube defines a plurality of corrugations.

25 In another aspect of the invention, there is provided a colonic overtube, the overtube:-

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having a proximal end for location externally of a colon, and a distal end for insertion into a colon; and

5 having a colonoscope lumen extending therethrough for advancing the overtube over a colonoscope;

the overtube being configured to maintain a sigmoid colon in a straightened configuration; and

10 the overtube defining at least one corrugation for kink resistance during advancement of the overtube through a colon.

The corrugated configuration of the overtube enables the overtube to advance through a potentially tortuous path in a colon without kinking.

15 Preferably the corrugation extends along the overtube in a convoluted manner.

In another case the corrugation extends around the overtube in a loop.

20 Ideally the overtube defines a plurality of corrugations.

In a preferred embodiment the overtube has stiffening means to maintain a sigmoid colon in a straightened configuration. The overtube may be of a sufficiently stiff material to maintain a sigmoid colon in a straightened configuration.

25 Desirably the overtube is at least partially of a low friction material.

30 Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

5 Fig. 1 is a perspective view of a colonic overtube according to the invention;

Fig. 2 is a side, partially cross-sectional view of a distal end of the overtube of Fig. 1;

10 Figs. 3 to 7 are side, partially cross-sectional views illustrating manufacture of the overtube of Figs. 1 and 2;

Fig. 8 is a schematic view illustrating lubrication of the overtube of Figs. 1 and 2;

15 Figs. 9 and 10 are perspective views of a colonoscope inserted through the overtube of Figs. 1 and 2;

20 Fig. 11 is a schematic view of a colon; and

Figs. 12 to 17 are schematic views of the colonoscope and overtube of Figs. 9 and 10 in use in the colon of Fig. 11.

25

Detailed Description

Referring to the drawings, there is illustrated a colonic overtube according to the invention. The overtube has a proximal end for location externally of a colon, and a distal end for insertion into the colon. A colonoscope lumen extends through the overtube for advancing the overtube over a colonoscope.

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The overtube is configured to maintain a sigmoid colon in a straightened configuration. Stiffening means may be provided to maintain the sigmoid colon in the straightened configuration.

5 The overtube defines at least one corrugation to resist kinking during advancement of the overtube through the colon.

10 A seal is provided at the distal end of the overtube to effect a seal between the overtube and the colonoscope extending through the colonoscope lumen. The seal may be fixed to the exterior surface of the overtube and extend inwardly to effect the seal between the overtube and the colonoscope. In one case, the seal may extend distally of the distal end of the overtube.

15 A rounded tip may be provided at the distal end of the overtube for atraumatic advancement of the overtube through the colon.

20 Referring to Figs. 1 and 2 there is illustrated a colonic overtube 1 according to the invention. The overtube 1 has a proximal end 2 for location, in use, externally of a colon, and a distal end 3 for insertion, in use, into a colon. A typical length for the overtube 1 is 0.5m.

A colonoscope lumen 4 extends through the overtube 1 to facilitate advancing the overtube 1 over a colonoscope, in use.

25 The overtube 1 is of a relatively stiff material, the material being chosen to ensure that the overtube 1 is sufficiently stiff to maintain a sigmoid colon in a straightened configuration during advancement of a colonoscope through the overtube, further distally into the descending colon. A low-friction coating of
30 polytetrafluoroethylene (PTFE) is provided around the interior and exterior

surfaces of the overtube 1 for ease of passage of the overtube 1 relative to a colonoscope and/or relative to a colon.

As illustrated in Figs. 1 and 2, the overtube 1 defines a corrugation 5 which is convoluted, the corrugation 5 extending along the overtube 1 from the proximal end 2 to the distal end 3. The corrugated configuration of the overtube 1 minimises the possibility of the relatively stiff overtube 1 kinking as the overtube 1 is advanced over a colonoscope through a colon.

A seal is provided at the distal end 3 of the overtube 1 for sealing between the overtube 1 and a colonoscope extending through the colonoscope lumen 4. The seal comprises a tubular silicone sheath 6, which is fixed to an exterior surface of the overtube 1 at the distal end 3 of the overtube 1 by means of a section of heat-shrink tubing 7. As illustrated in Fig. 2, the sheath 6 extends inwardly at the distal end 3 of the overtube 1 to effect a seal to a colonoscope, and then distally of the distal end 3 of the overtube 1.

The sheath 6 is folded over to define an inner sealing layer 9, and an outer sealing layer 8, which surrounds the inner sealing layer 9. The heat-shrink tubing 7 is provided between the inner and outer layers 9, 8.

The overtube 1 comprises another section of heat-shrink tubing 10 fixed to an exterior surface of the overtube 1 at the distal end 3 of the overtube 1. The tubing 10 extends around the distal end 3 of the overtube 1 partially into the colonoscope lumen 4 to define a rounded tip at the distal end 3 of the overtube 1. In this manner, the rounded tip tubing 10 ensures that there are no sharp edges at the distal end 3 of the overtube 1 for atraumatic advancement of the overtube 1 through a colon.

Manufacture of the overtube 1 is described with reference to Figs. 3 to 7. The overtube 1 is extruded to a typical length of 0.5m with the convoluted corrugation 5 extending along the overtube 1 from the proximal end 2 to the distal end 3.

5 The section of heat-shrink tubing 10 is positioned around the distal end 3 of the overtube 1, partially overlapping the distal end 3, and a mandrel 11 is partially inserted into the colonoscope lumen 4 from the distal end 3 (Fig. 3). Heat is applied to shrink the tubing 10 down partially onto the exterior surface of the overtube 1 and partially onto the mandrel 11.

10 The mandrel 11 is moved proximally, further into the colonoscope lumen 4 while rotating the mandrel 11 (Fig. 4). By moving the mandrel 11 proximally, the tubing 10 is folded around the distal end 3 of the overtube 1 partially into the colonoscope lumen 4, and by rotating the mandrel 11, the tubing 10 is detached
15 from the mandrel 11. The mandrel 11 is then removed from the colonoscope lumen 4.

A proximal end 12 of the tubular sheath 6 is rolled inwardly and the sheath 6 is positioned around the distal end 3 of the overtube 1, partially overlapping the
20 distal end 3. The tubular sheath 6 has a smaller diameter than the overtube 1, so the sheath 6 is stretched to position it around the overtube 1.

The section of the heat-shrink tubing 7 is positioned around the sheath 6 distally of the rolled proximal end 12 (Fig. 5), and heat is applied to shrink the tubing 7
25 down onto the sheath 6 to fix the sheath 6 to the exterior surface of the overtube 1 (Fig. 6). The rolled proximal end 12 is then rolled out distally over the tubing 7, off the distal end 3 of the overtube 1 to define the outer sealing layer 8 which surrounds the inner sealing layer 9 (Fig. 7).

30 The assembled colonic overtube 1 is now ready for use. A lubricant 13 is liberally applied both externally and internally to the overtube 1 (Fig. 8) to ease passage of

the overtube 1 relative to a colonoscope and/or relative to a colon. A colonoscope 14 is inserted into the colonoscope lumen 4 at the proximal end 2 of the overtube 1 and advanced through the lumen 4 until a distal end 15 of the colonoscope 14 emerges from the distal end 3 of the overtube 1 through the sealing sheath 6 (Fig. 9).

The colonoscope 14 has a power/light source 16 at a proximal end 17 of the colonoscope 14, and the overtube 1 is moved proximally over the colonoscope 14 until the proximal end 2 of the overtube 1 is adjacent the power/light source 16 (Fig. 10).

The colonoscope 14 is now ready for insertion into a colon of a patient. A typical colon 18 is illustrated in Fig. 11, in which the rectum 19 leads from the anus 20 to the sigmoid colon 21. The redundancy in the sigmoid colon 21 may be seen in Fig. 11. The descending colon 22 leads from the sigmoid colon 21 to the transverse colon 23.

The distal end 15 of the colonoscope 14 is inserted through the anus 20 into the rectum 19, and the colonoscope 14 is advanced into the sigmoid colon 21 (Fig. 12). As the colonoscope 14 advances through the floppy sigmoid colon 21, a loop may form in the sigmoid colon 21, which results in stretching of the mesentery 24 to which the sigmoid colon 21 is attached (Fig. 13).

When the distal end 15 of the colonoscope 14 reaches the proximal end of the descending colon 22, the distal end 15 is anchored in the fixed descending colon 22, and the sigmoid colon 21 is straightened by manipulating the colonoscope 14 (Fig. 14). When the sigmoid colon 21 has been straightened, the anchor is released (Fig. 15).

The distal end 3 of the overtube 1 is inserted through the anus 20 into the rectum 19, and the overtube 1 is then advanced through the straightened sigmoid colon

21 until the distal end 3 of the overtube 1 is at the proximal end of the descending colon 22 (Fig. 16). The overtube 1 is advanced through the colon 18 over the colonoscope 14, as illustrated in Fig. 16. In this manner, the colonoscope 14 acts as a guiding track for the overtube 1 advancing through the colon 18.

5

The sheath 6 effects a double-layered seal between the overtube 1 and the colonoscope 14, over which the overtube 1 advances, at the distal end 3 of the overtube 1. This seal ensures that parts of the interior wall of the colon 18 do not become trapped between the colonoscope 14 and the overtube 1 as the overtube 1 is advanced over the colonoscope 14, and thus prevents shearing off of any parts of the colon wall, or puncturing the colon wall, or any other damage to the interior wall of the colon 18.

10

The sealing sheath 6 also prevents faeces or other bodily materials leaking between the colonoscope 14 and the overtube 1 proximally out through the anus 20.

15

With the overtube 1 extended through the straightened sigmoid colon 21, as illustrated in Fig. 16, the colonoscope 14 may then be advanced further distally through the descending colon 22 and into the transverse colon 23 (Fig. 17). The overtube 1 acts as a splint, and is sufficiently stiff to maintain the sigmoid colon 21 in the straightened configuration.

20

The splinting overtube 1 ensures that further advancement of the colonoscope 14 through the descending colon 22 and into the transverse colon 23 is possible by preventing loops from reforming in the sigmoid colon 21. In this manner, the overtube 1 minimises the pain or discomfort experienced by the patient during this procedure.

25

It will be appreciated that the corrugated overtube may be provided in alternative forms to that described above with reference to Figs. 1 to 17. For example, the

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corrugation on the overtube may extend around the overtube in a loop or hoop, and/or more than one corrugation may be provided on the overtube.

5 The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.

Claims

1. A colonic overtube, the overtube:-

5 having a proximal end for location externally of a colon, and a distal end
for insertion into a colon; and

having a colonoscope lumen extending therethrough for advancing the
overtube over a colonoscope;

10 the overtube being configured to maintain a sigmoid colon in a
straightened configuration; and

the overtube comprising a seal at the distal end of the overtube for sealing
15 between the overtube and a colonoscope extending through the
colonoscope lumen.
2. An overtube as claimed in claim 1 wherein the seal is fixed to an exterior
20 surface of the overtube, the seal extending inwardly to effect a seal between
the overtube and a colonoscope extending through the colonoscope lumen.
3. An overtube as claimed in claim 1 or 2 wherein the seal extends distally of
the distal end of the overtube.
- 25 4. An overtube as claimed in any of claims 1 to 3 wherein the seal comprises
an inner sealing layer and an outer sealing layer surrounding the inner
sealing layer.
- 30 5. An overtube as claimed in claim 4 wherein the seal comprises a tubular
sheath, the sheath being folded over to define the inner sealing layer and
the outer sealing layer.

6. An overtube as claimed in any of claims 1 to 5 wherein the overtube comprises a rounded tip at the distal end of the overtube for atraumatic advancement of the overtube through a colon.
- 5
7. An overtube as claimed in claim 6 wherein the tip is fixed to an exterior surface of the overtube, the tip extending around the distal end of the overtube at least partially into the colonoscope lumen.
- 10
8. An overtube as claimed in any of claims 1 to 7 wherein the overtube defines at least one corrugation for kink resistance during advancement of the overtube through a colon.
- 15
9. An overtube as claimed in claim 8 wherein the corrugation extends along the overtube in a convoluted manner.
10. An overtube as claimed in claim 8 wherein the corrugation extends around the overtube in a loop.
- 20
11. An overtube as claimed in any of claims 8 to 10 wherein the overtube defines a plurality of corrugations.
12. A colonic overtube, the overtube:-
- 25
- having a proximal end for location externally of a colon, and a distal end for insertion into a colon; and
- having a colonoscope lumen extending therethrough for advancing the overtube over a colonoscope;
- 30

the overtube being configured to maintain a sigmoid colon in a straightened configuration; and

the overtube defining at least one corrugation for kink resistance during advancement of the overtube through a colon.

13. An overtube as claimed in claim 12 wherein the corrugation extends along the overtube in a convoluted manner.
14. An overtube as claimed in claim 12 wherein the corrugation extends around the overtube in a loop.
15. An overtube as claimed in any of claims 12 to 14 wherein the overtube defines a plurality of corrugations.
16. An overtube as claimed in any preceding claim wherein the overtube has stiffening means to maintain a sigmoid colon in a straightened configuration.
17. An overtube as claimed in claim 16 wherein the overtube is of a sufficiently stiff material to maintain a sigmoid colon in a straightened configuration.
18. An overtube as claimed in any preceding claim wherein the overtube is at least partially of a low friction material.
19. An overtube substantially as hereinbefore described with reference to the accompanying drawings.

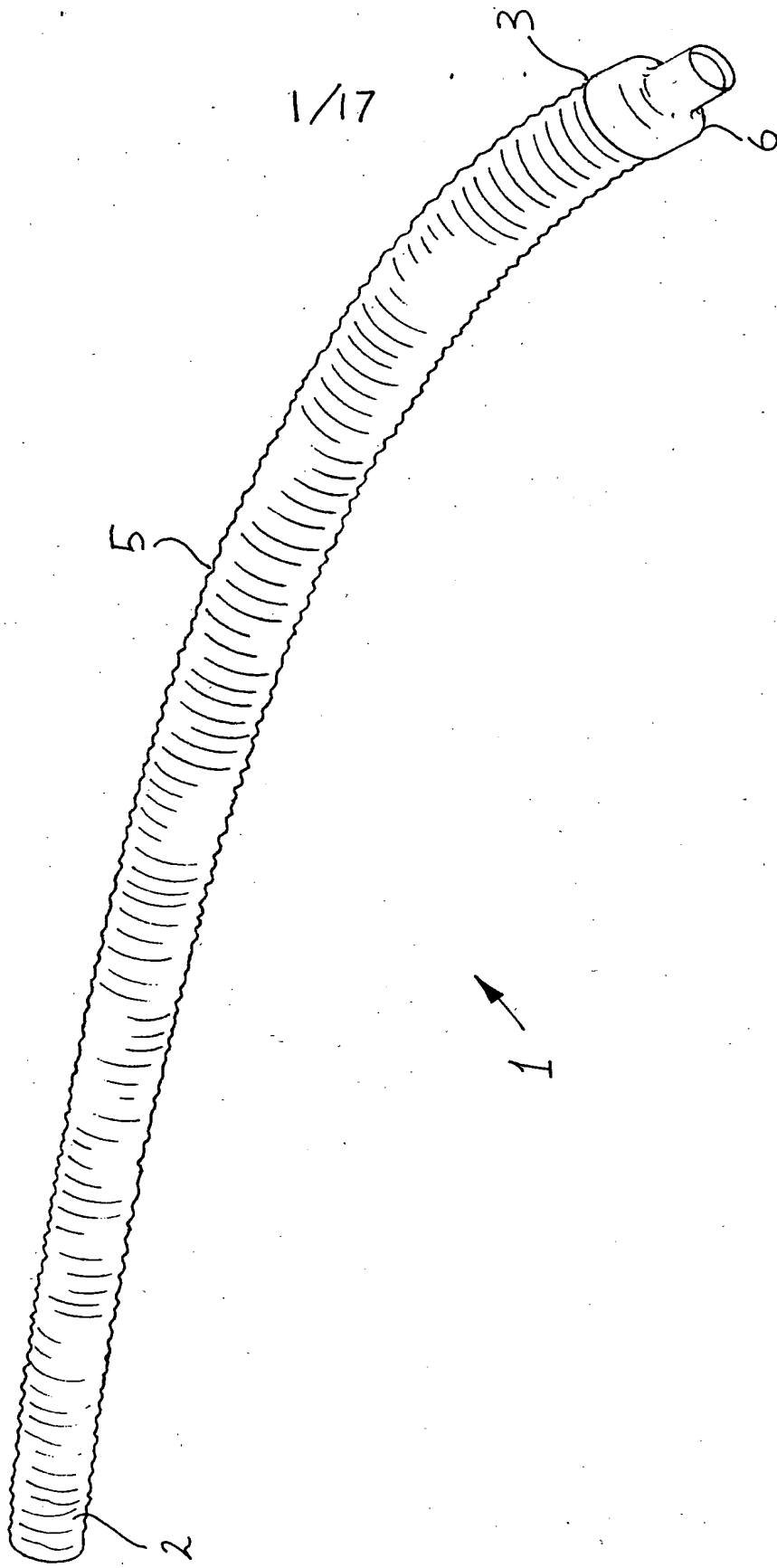


Fig. 1

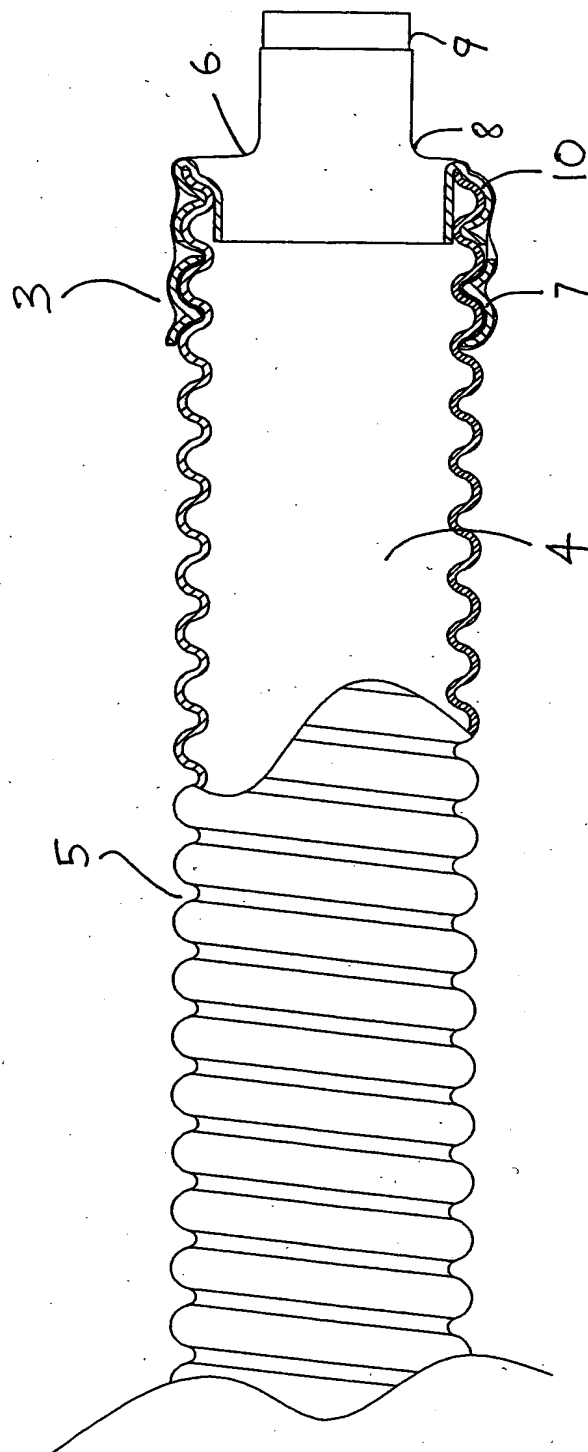


Fig. 2

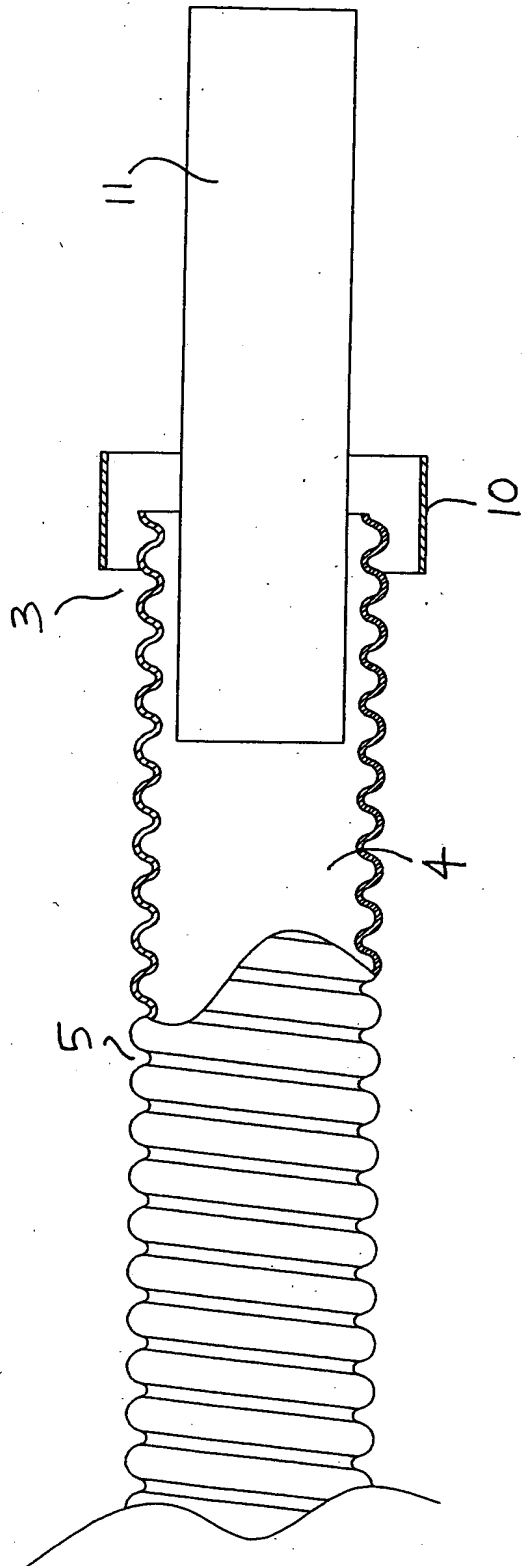


Fig. 3

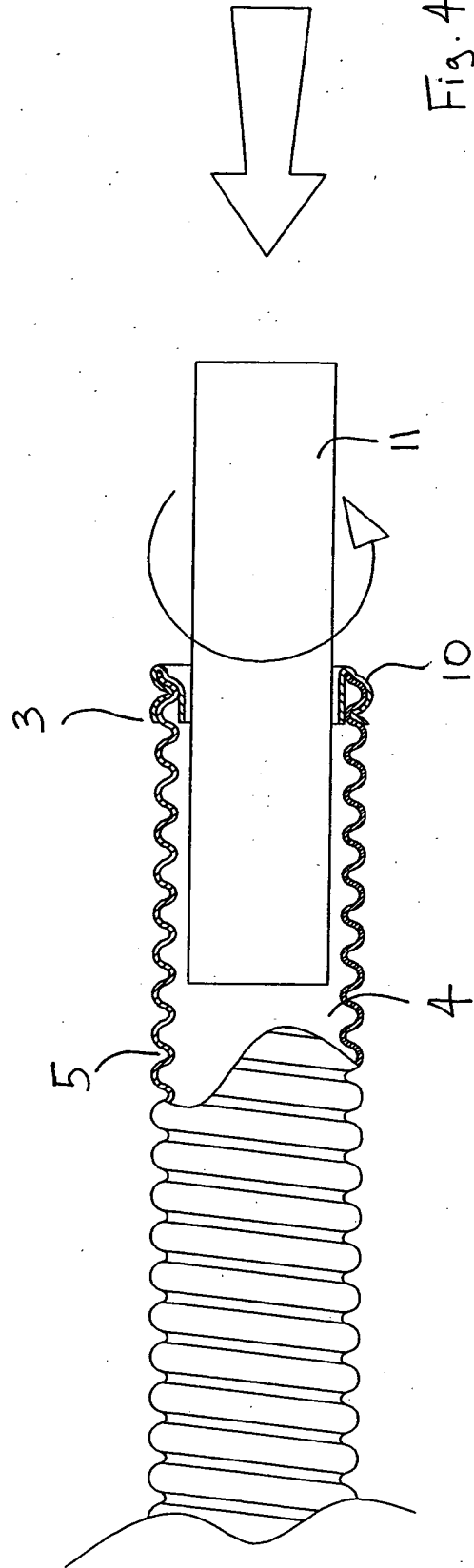
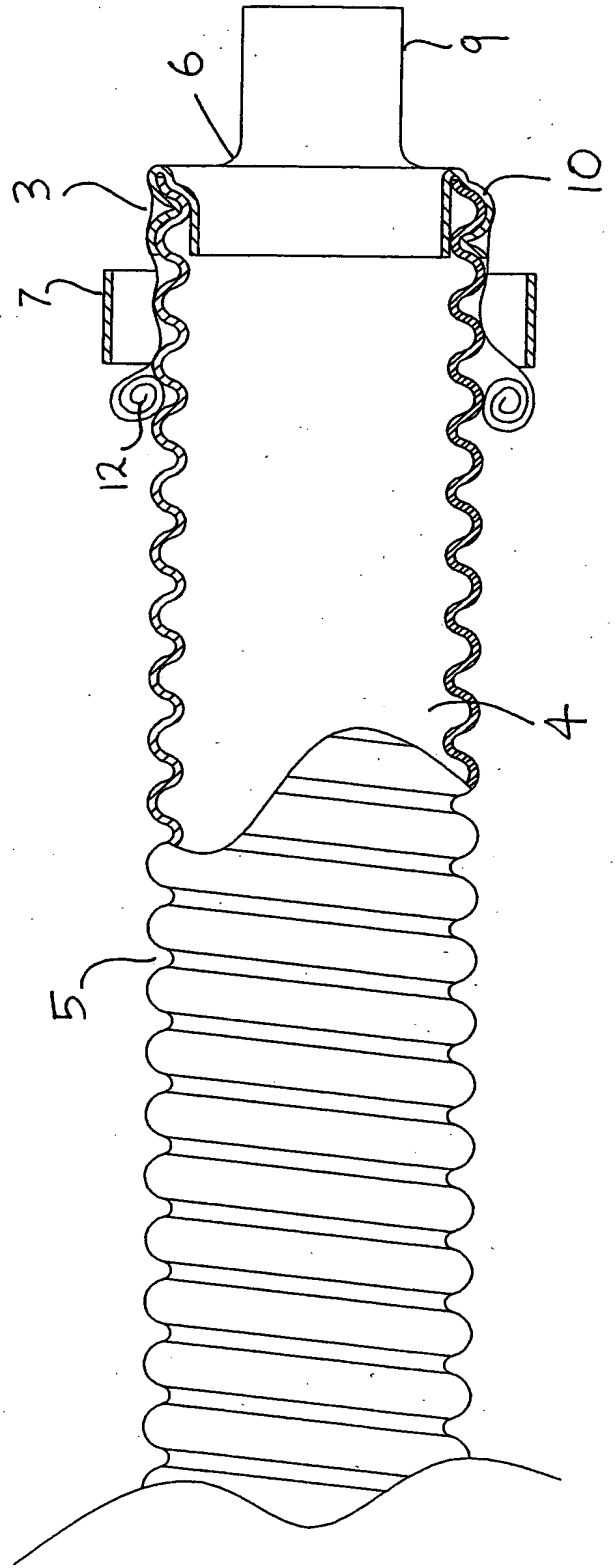


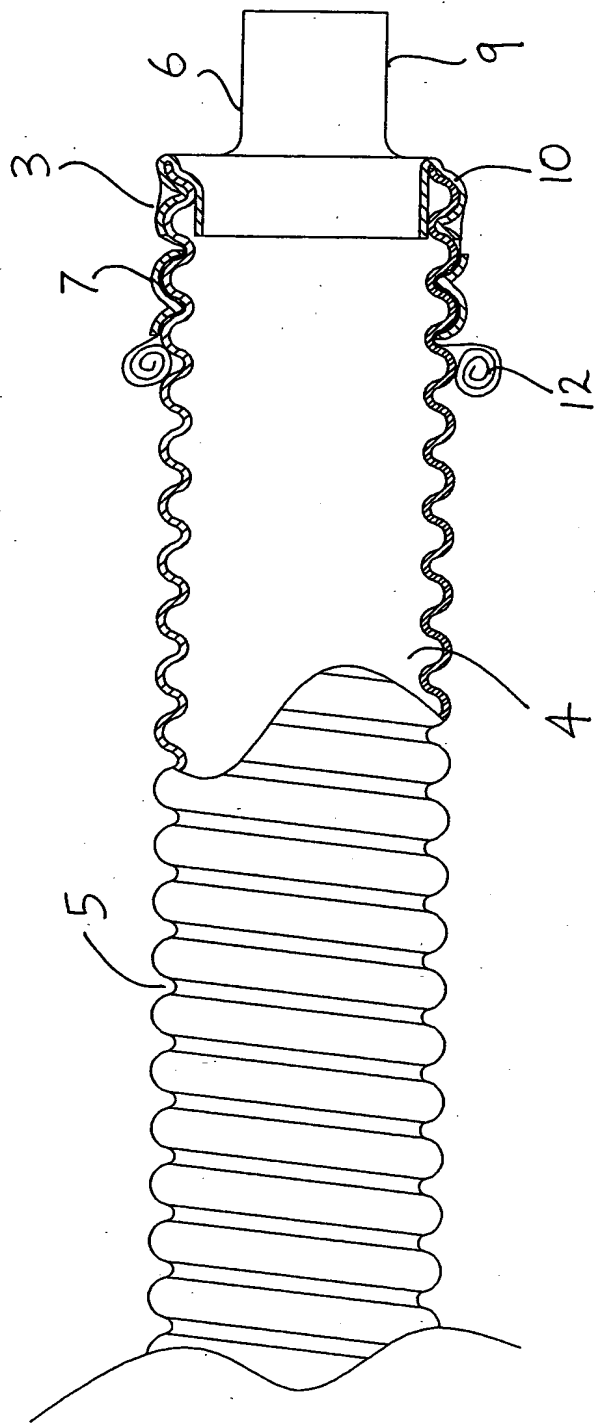
Fig. 4

Fig. 5



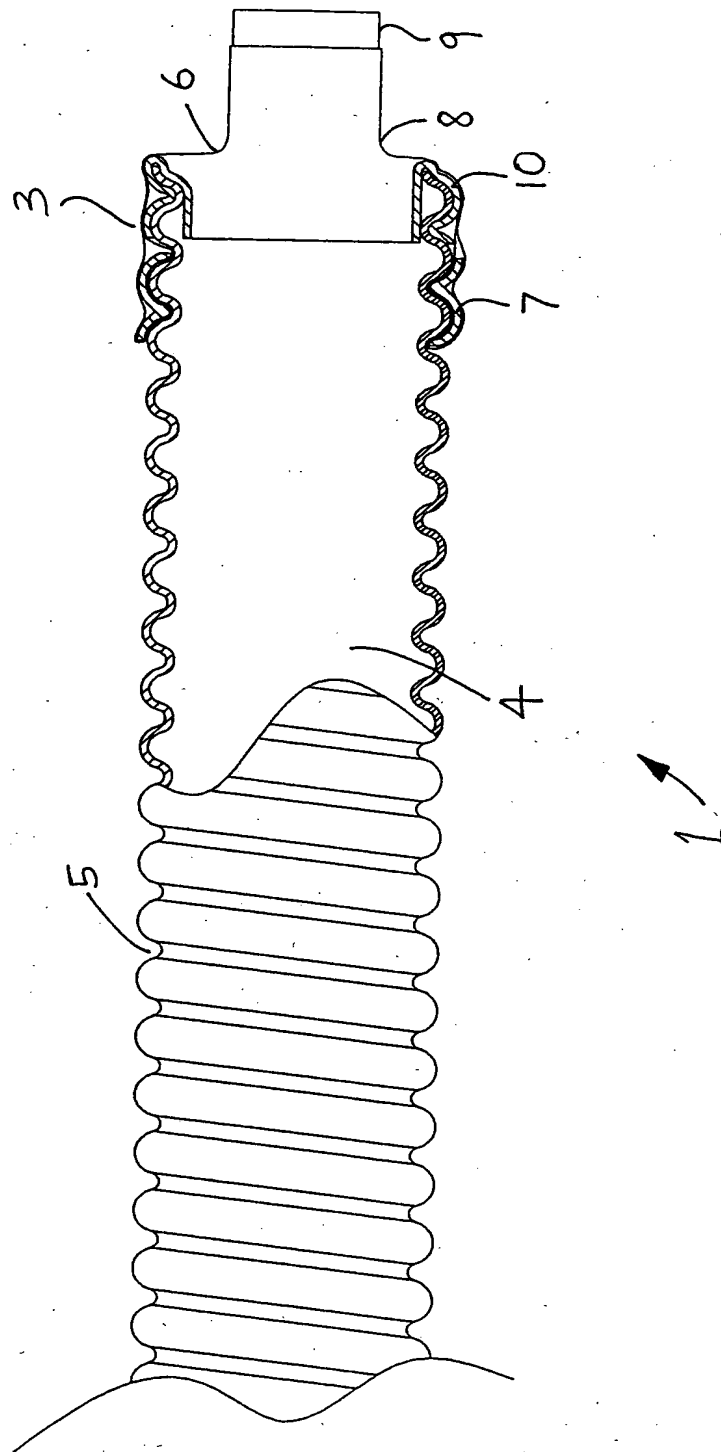
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Fig. 6



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Fig. 7



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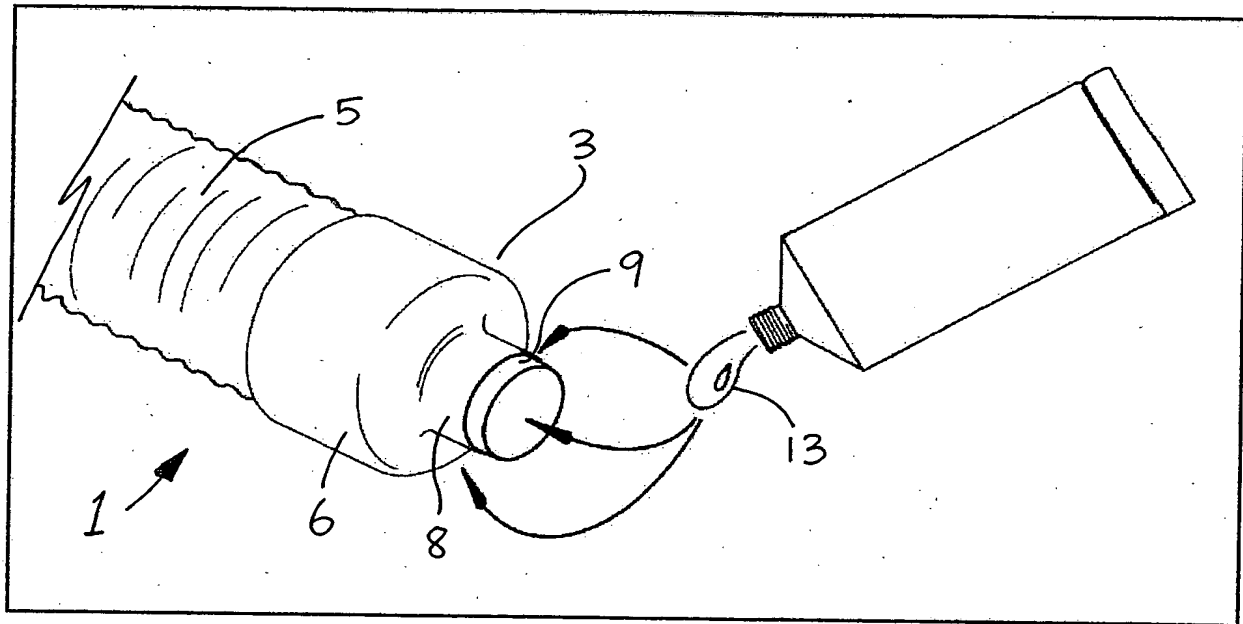


Fig. 8

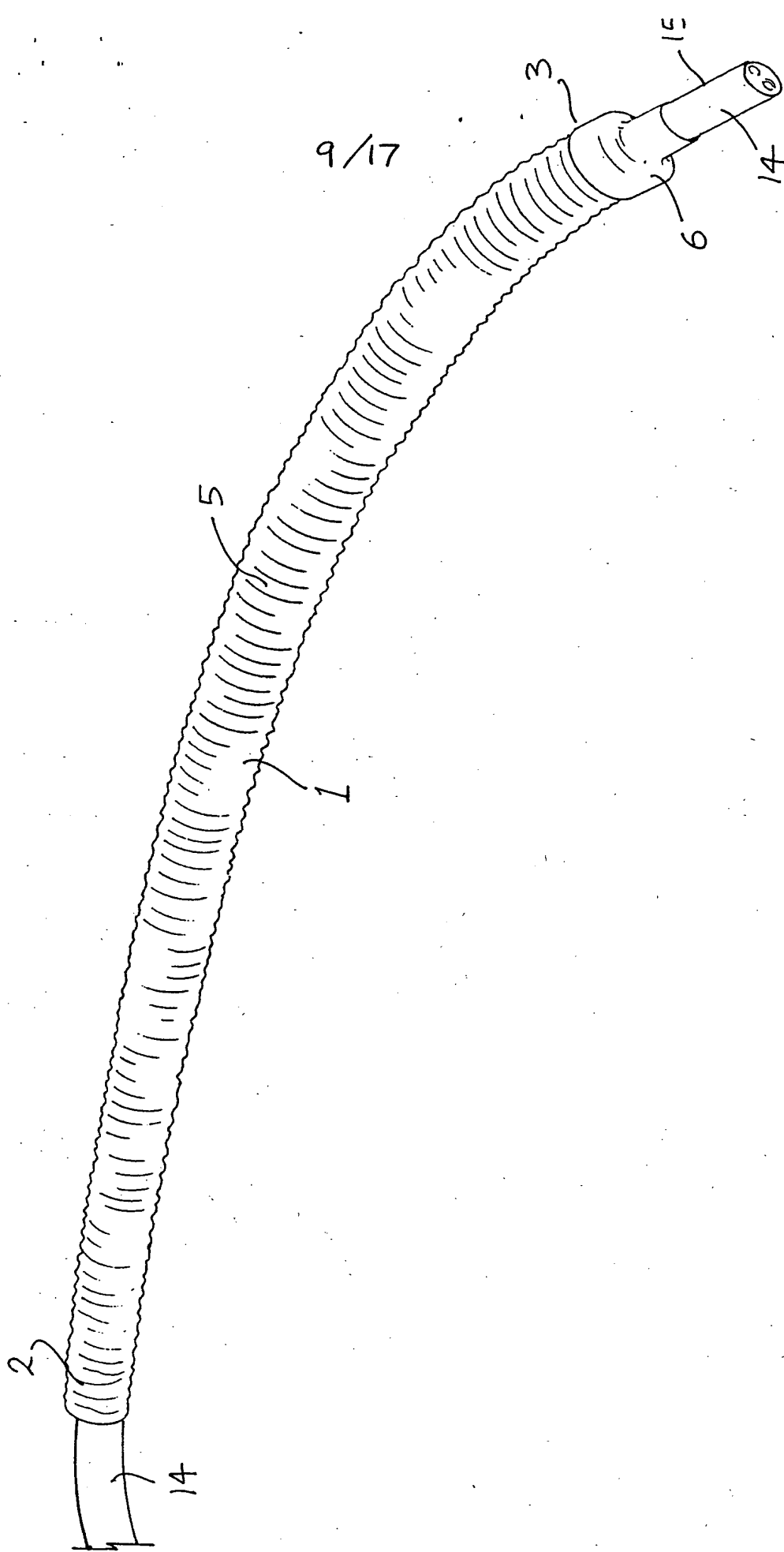


Fig. 9

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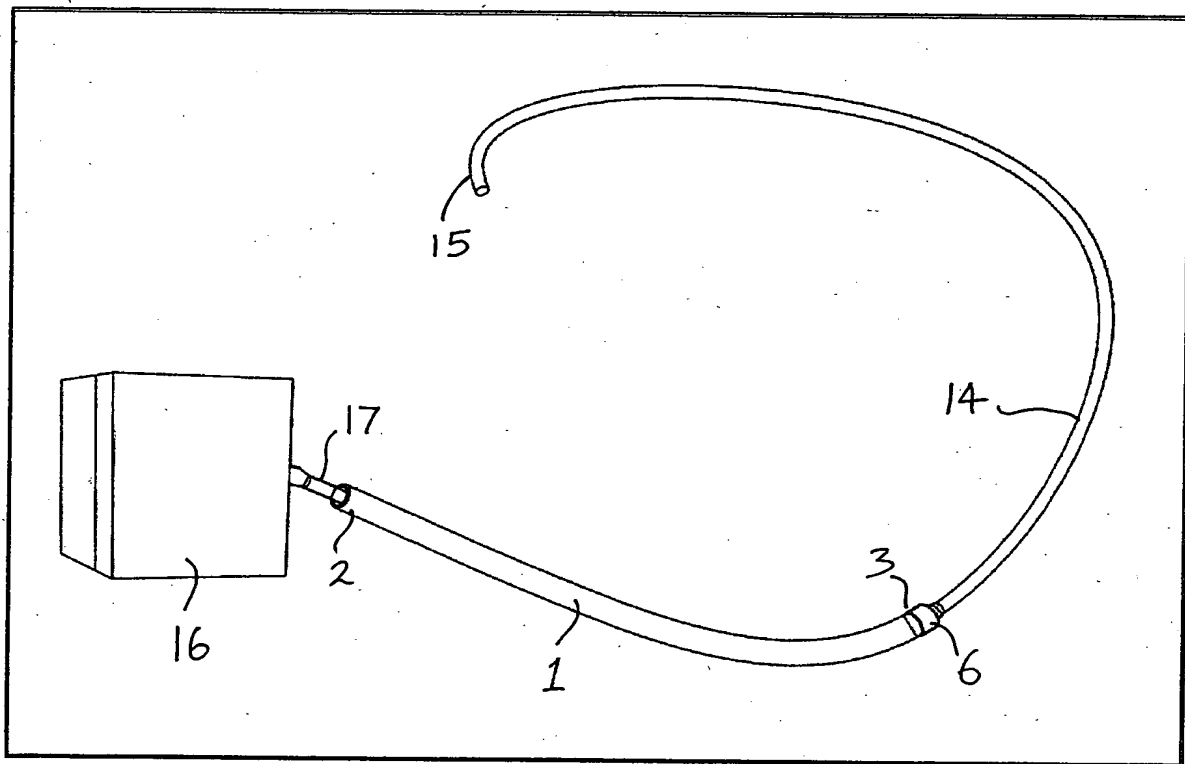


Fig. 10

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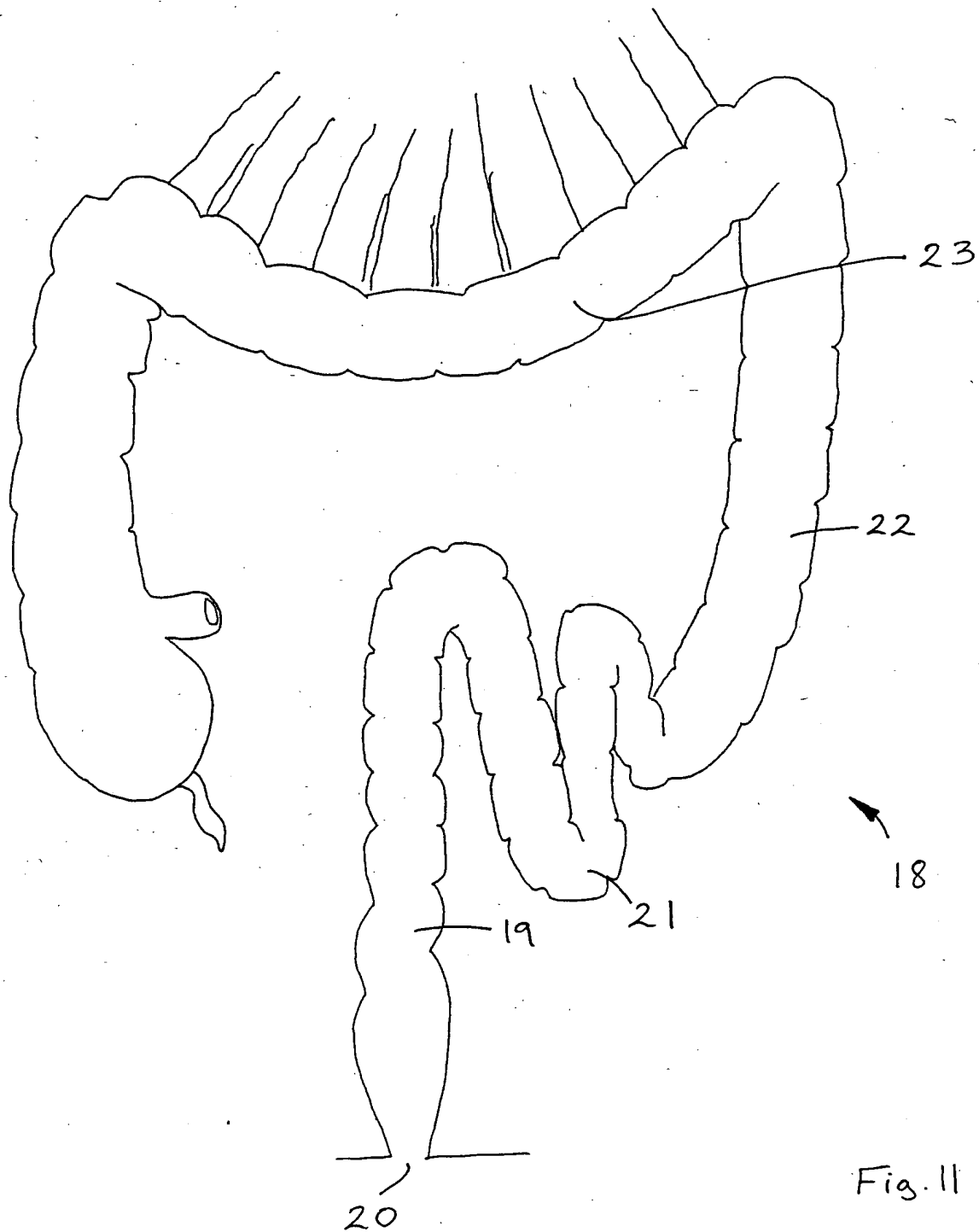


Fig. 11

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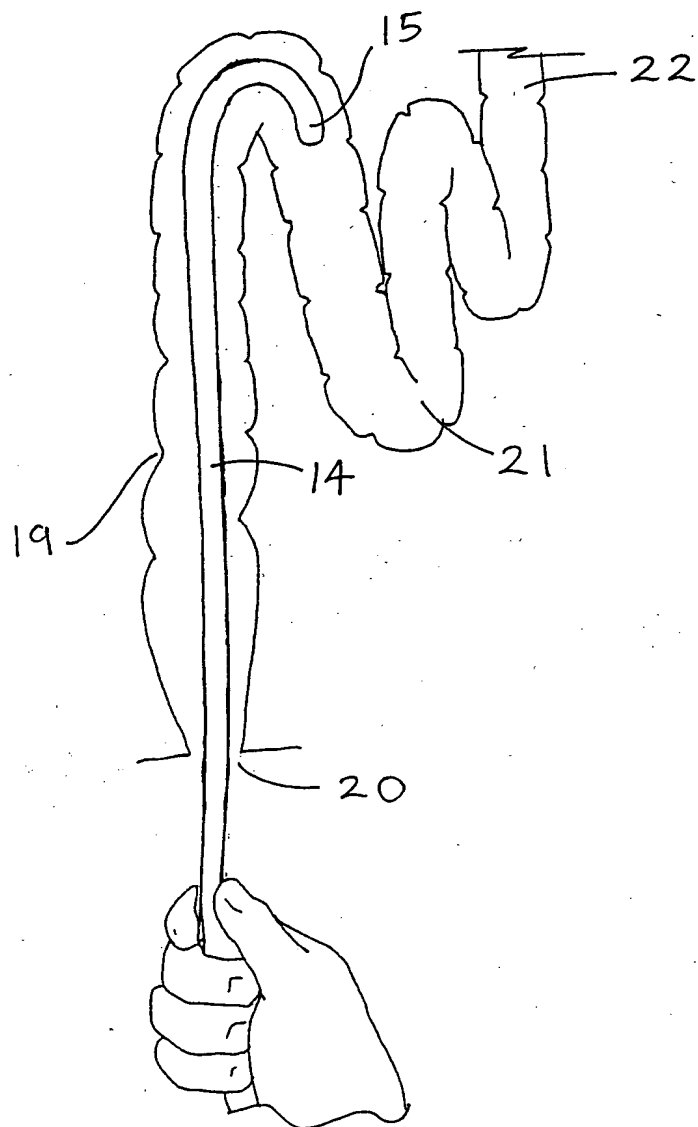


Fig. 12

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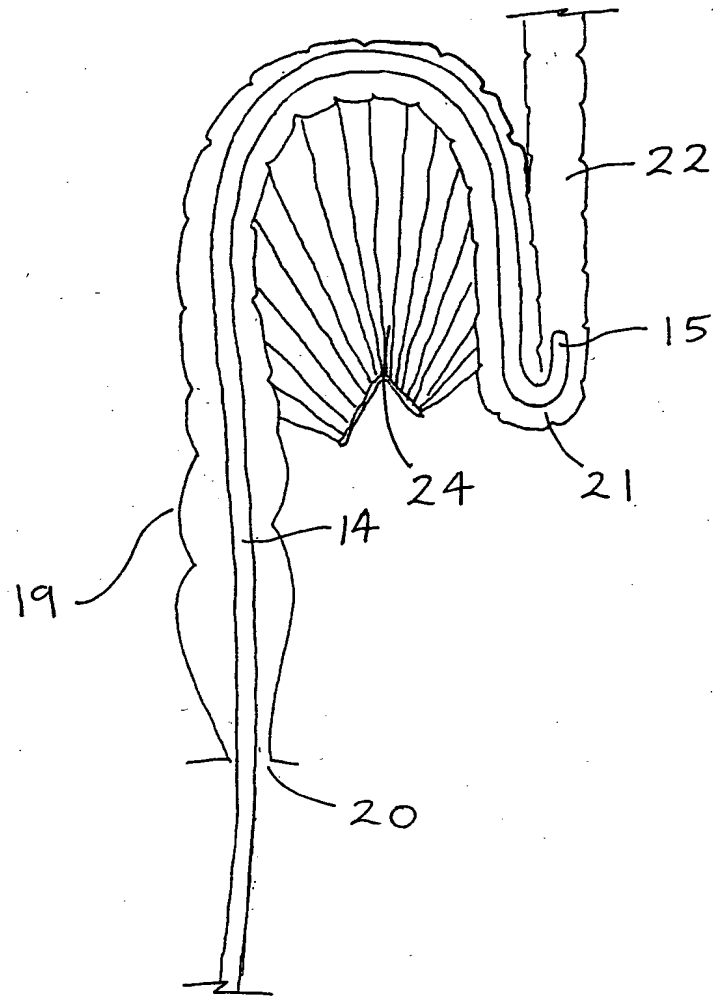


Fig. 13

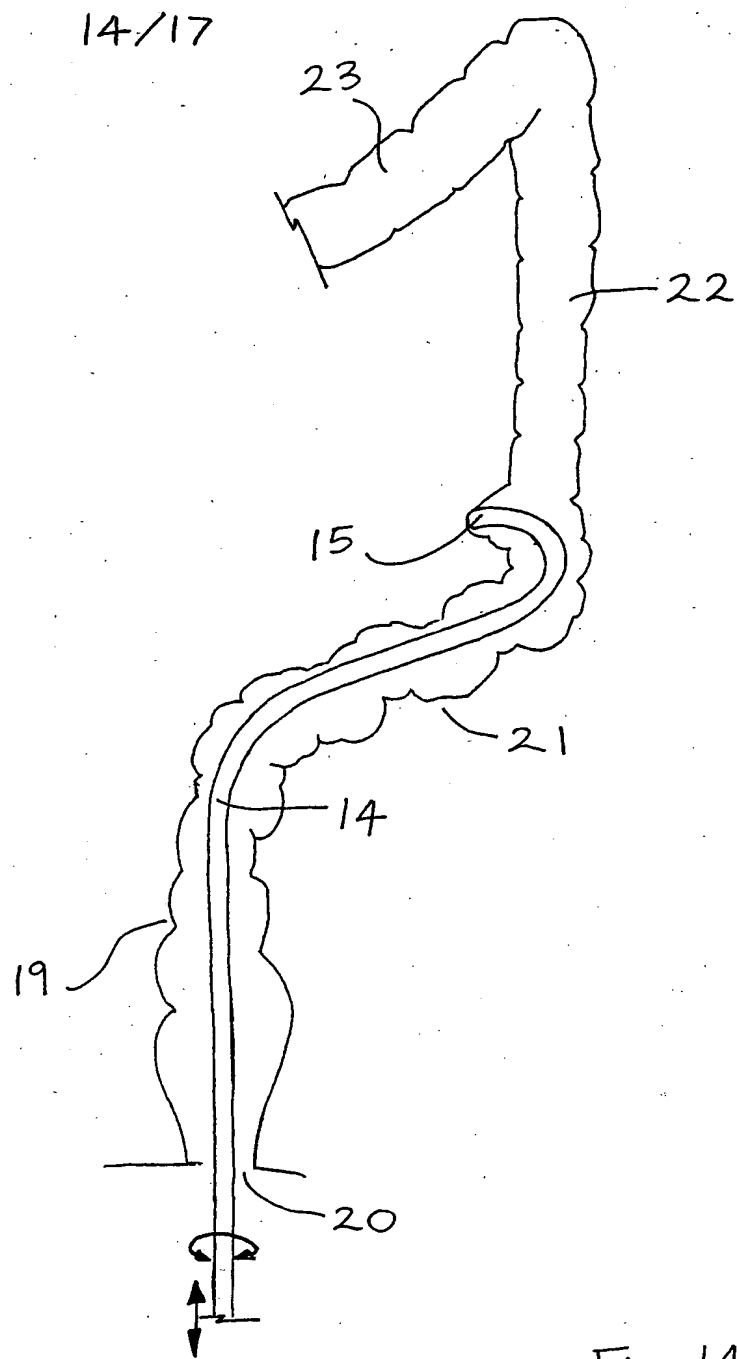


Fig. 14

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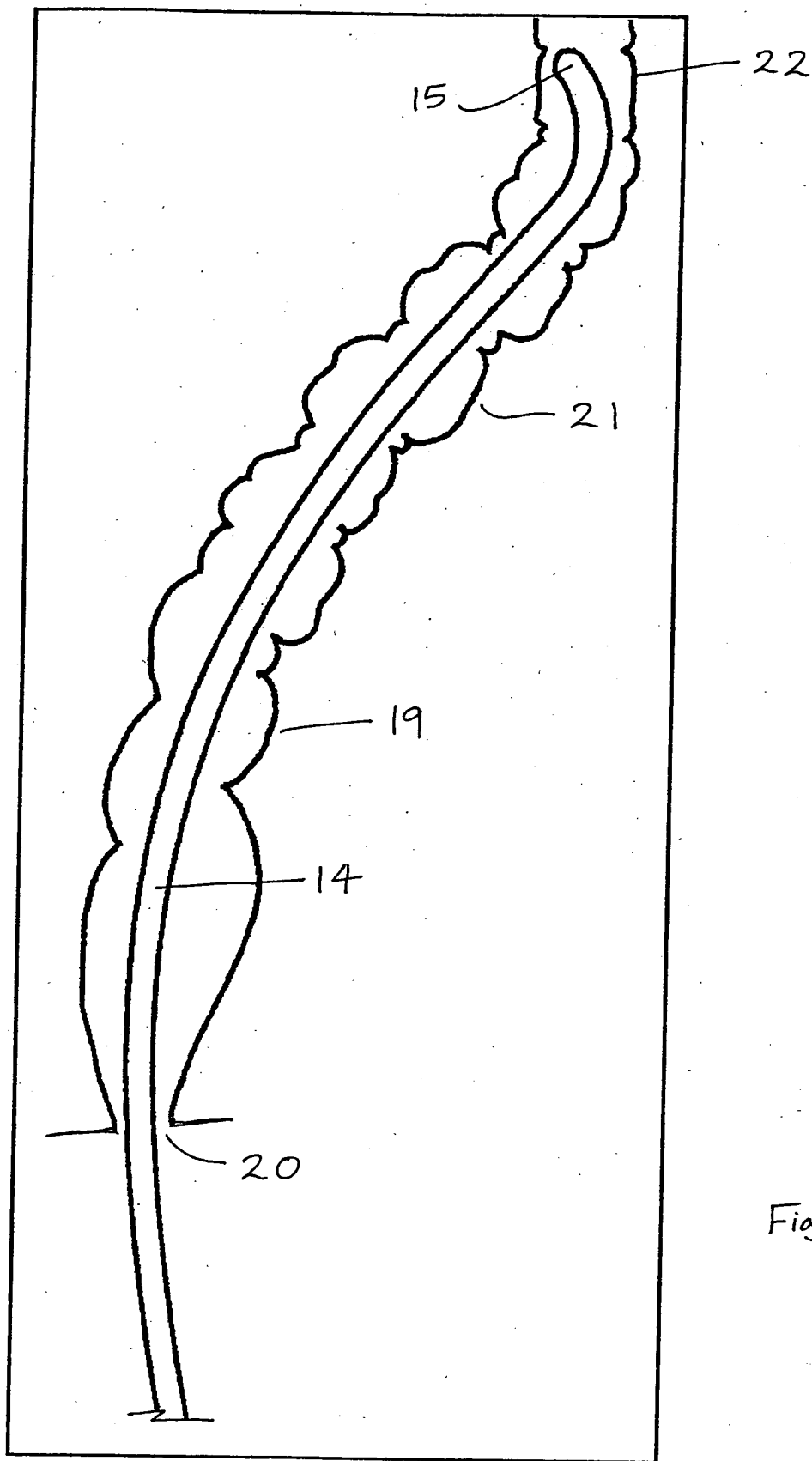


Fig. 15

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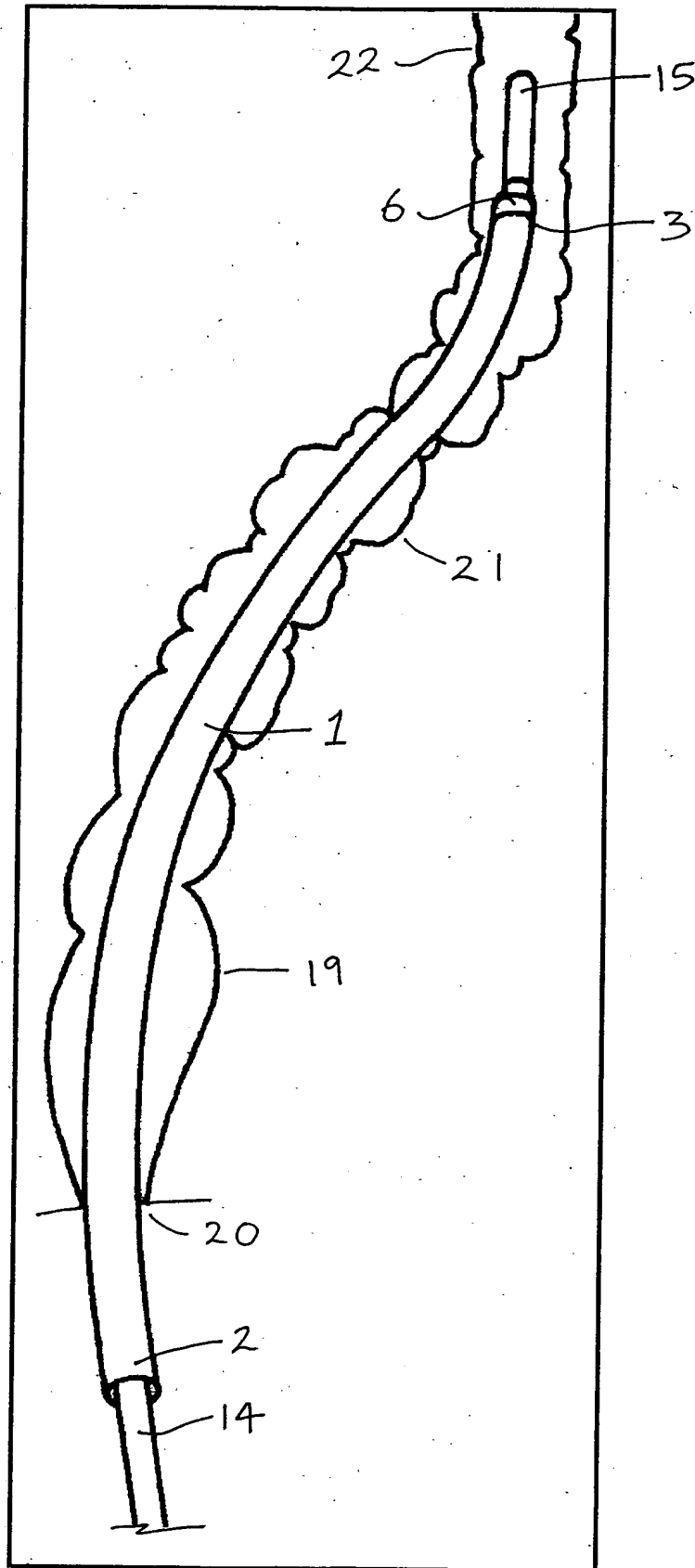


Fig. 16

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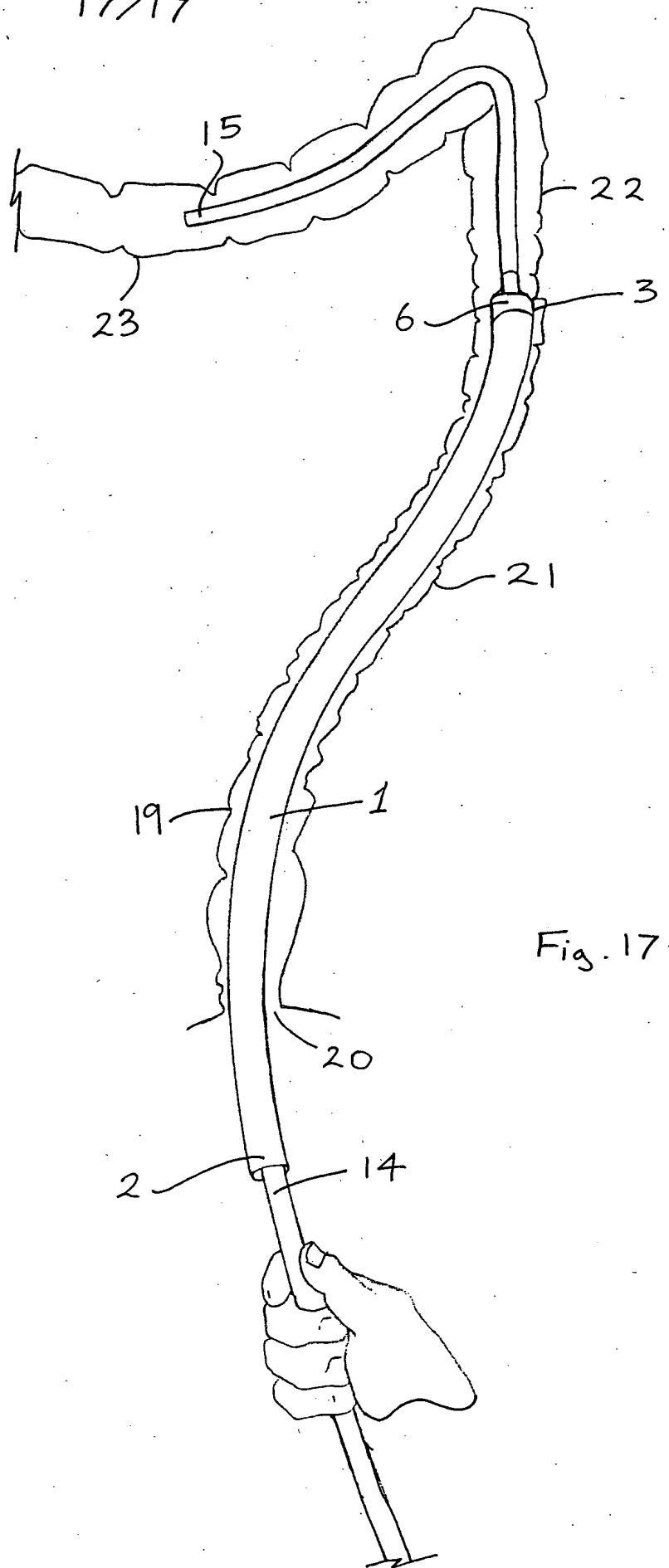


Fig. 17